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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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10/10/01 10/10/01 MELLER

EXAMINER

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10/10/01
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U.S. PATENT AND TRADEMARK OFFICE
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ART UNIT	PAPER NUMBER
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1640

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09/343 001

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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1644 18

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- Responsive to communication(s) filed on 6/19/01
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s) or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- Claim(s) 145-166 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 145-166 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

- All Some* None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) _____
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of Reference Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

DETAILED ACTION

1. Applicant's amendment, filed 6/19/01 (Paper No. 11), has been entered.
Claims 1 and 102-144 have been canceled. Claims 2-101 have been canceled previously.
Claims 145-166 have been added.
2. It is noted that applicant has indicated that vasculitis has written description on page 19, lines 6-8 of priority application USSN 08/566,238, filed 12/1/95.
3. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Office Action will be in response to applicant's arguments, filed 6/19/01 (Paper No. 11).
The rejections of record can be found in the previous Office Action (Paper No. 8).
4. Upon reconsideration of applicant's amended claims and arguments, filed 6/19/01 (Paper No. 11), the previous rejections under 35 U.S.C. 112, first and second paragraphs, and 35 U.S.C. § 102(e) with respect to Noelle et al. (U.S. Patent No. 5,683,693) have been rendered moot or have been withdrawn.
5. Claims 145-153 and 156-163 are rejected under 35 U.S.C. § 102(e) as being anticipated by Black et al. (U.S. Patent No. 6,001,358) (see entire document).

Black et al. teach methods of inhibiting vasculitis (column 33, line 1 and 64) with CD40L-specific antibodies (e.g. gp39-specific and 5C8-specific antibodies), including the use of recombinant antibodies and fragments (columns 13-22) in conventional methods including various dosages and modes of administration to meet the needs of the patient and the nature of the disease or condition (columns 34-38).

In addition, Black et al. teach that it was recognized by the ordinary artisan to administering effective amounts (0.05 / 0.5 - 10 / 100 milligrams per kilogram body weight; column 36) and by modes and routes of administration (e.g. parenteral; column 36) and other known variables, which is dictated by the therapeutic or prophylactic effect desired (see columns 34 - 38) encompassed by the claimed methods.. Also, Black et al. teach that it was recognized by the ordinary artisan that the optimal quantity and spacing of individual dosages of an antibody will be determined by the nature and extent of the condition being treated, the form , route and site of administration, which can be determined by conventional techniques (see columns 35-36, overlapping paragraph).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations addressed by the applicant would be inherent properties of the referenced methods/antibodies. Also, see Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgram, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999); Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

6. Claims 145-166 are rejected under 35 U.S.C. § 103 as being unpatentable over Black et al. (U.S. Patent No. 6,001,358) in view of Lederman et al. (WO 93/09812; 1449) essentially for the reasons of record set forth in Paper No. 8.

Black et al. teach methods of inhibiting vasculitis (column 33, line 1 and 64) with CD40L-specific antibodies (e.g. gp39-specific and 5C8-specific antibodies), including the use of recombinant antibodies and fragments (columns 13-22) in conventional methods including various dosages and modes of administration to meet the needs of the patient and the nature of the disease or condition (columns 34-38).

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Lederman et al.(WO 93/09812) teach the inhibition of various immune cell interactions associated with 5C8 via 5C8-specific antibodies, including recombinant antibodies and methods of screening for said antibodies (see entire document) The referenced 5C8 antigen specificity was also known as CD40L at the time this publication was available

It was well known and practiced at the time the invention was made to make and modify antibodies for human use, including the generation of various antigen-binding fragments (e.g. Fab, single chain antibody) as well as recombinant antibodies (e.g. chimeric, humanized and primatized) encompassed by the claimed methods. It was art known methods to employ recombinant forms of antibodies to increase half-life and efficacy of antibody-mediated therapies and to screen antibodies of interest.

Given the teachings of the prior art and the well known practice by the ordinary artisan at the time the invention was made; one of ordinary skill in the art would have provide antagonistic CD40L-specific antibodies to treat vasculitis and to meet the needs of the patients. Given the nature of the condition of vasculitis, it would have been well within in the purview of ordinary artisan at the time the invention was made to provide said antagonistic antibodies at various intervals and timing schedules (e.g. daily, weekly) including those encompassed by the claimed methods. For example, Black et al. teach that the number of doses of antagonistic antibody given per day for a defined number of days can be ascertained by those skill in the art using conventional course of treatment determination tests (e.g. column 36, paragraph 1) as well as single or multiple administrations (column 38, paragraph 3) (columns 34-38). Again, the claimed dosages and routes of administration were known and practiced at the time the invention was made and/or would have been encompassed in providing for sufficient therapeutic intervention depending on the vasculitis patient's needs at the time the invention was made.

One of ordinary skill in the art at the time the invention was made would have been motivated to select the ability of CD40L-specific antibodies to inhibit vasculitis. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

7. Applicant's arguments, filed 6/19/01 (Paper No. 11), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant argues that Black et al. fails to disclose each and every element of the newly submitted claims, particularly specific dosages and administration regimens and modalities of the instant claimed methods.

In addition, applicant argues that the prior art at most constitutes a suggestion to try.

In contrast to applicant's arguments, the prior art clearly anticipate or render obvious the claimed methods of treating vasculitis with CD40L-specific antibodies at the time the invention was made, as indicated of record and above.

In contrast to applicant's assertions of the rejection is based upon an "obvious-to-try" standard; it is by now well understood that the ultimate conclusion of law that claimed subject matter as a whole would have been obvious under 35 USC 103 may at times properly be drawn from an inference of fact arising from prior art teachings which could be considered an inference that it would be "obvious to try" that which is claimed. In re O'Farrell, 853 F.2d 894, 7 USPQ 2d 1973 (Fed. Cir. 1988); Contour Saws Inc. v. Starrett Co., 444 F. 2d 433, 170 USPQ 433 (Ct.App. 1977); In re Marzocchi, 439 F. 2d 220, 169 USPQ 367 (CCPA 1977); In re Lindell, 385 F. 2d 435, 155 USPQ 521 (CCPA 1967). The evidence of purported unobvious results of record in this application is insufficient to overcome the inference of fact in this case.

Therefore the above claims remain rejected under 35 USC 102 and 103 for the reasons above and also those set forth in the previous Office action.

Applicant's arguments are not found persuasive.

8. Claims 145- 146 are objected to, given that the proper designation is " $F(ab)_2$ " and not " $F(ab)'2$ ".

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phillip Gambel

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
September 10, 2001